

The invention in which an exclusive right is claimed is defined by the following:

1. A hollow microneedle comprising:

- (a) a generally conical-shaped body having a beveled, non-coring tip, said tip being sharp and able to pierce tissue;
- (b) said conical body further having a broad base formed of a substrate at an opposite end from the tip; and
- (c) a fluid channel extending through the conical-shaped body, providing fluid communication between said broad base and said tip.

2. The hollow microneedle of Claim 1, wherein a height of the microneedle, which is defined as a distance from said broad base to said tip, is within a range from about 50 μm to about 100 μm .

3. The hollow microneedle of Claim 1, wherein a height of each microneedle, which is defined as a distance from said broad base to said tip, is substantially less than a width of said broad base.

4. The hollow microneedle of Claim 1, wherein said hollow microneedle comprises silicon.

5. Apparatus for conveying a fluid transcutaneously, comprising:

- (a) a substrate, said substrate comprising at least one inlet, and a plurality of outlets in fluid communication with said at least one inlet; and
- (b) a plurality of microneedles arranged in an array and extending substantially outwardly from said substrate, each microneedle including:
 - (i) a generally conical-shaped body having a beveled, non-coring tip, said tip being sharp and able to pierce tissue;
 - (ii) said conical body further having a broad base formed of the substrate at an opposite end from the tip; and
 - (iii) a fluid channel extending through the conical-shaped body, providing fluid communication between one of the outlets disposed said broad base is formed from the substrate and said tip.

6. The apparatus of Claim 5, wherein a height of each microneedle, which is defined as a distance from said broad base to said tip, is within a range from about 50 μm to about 100 μm .

7. The apparatus of Claim 5, wherein a height of each microneedle, which is defined as a distance from said broad base to said tip, is substantially less than a width of said broad base.

8. The apparatus of Claim 5, wherein at least one of said substrate and the microneedles comprises silicon.

9. The apparatus of Claim 5, wherein said array of the microneedles is integrally formed from said substrate.

10. A method of manufacturing a hollow microneedle, comprising the steps of:

- (a) providing a substrate;
- (b) forming a fluid channel within said substrate, such that said fluid channel passes through said substrate; and
- (c) removing a substantial portion of said substrate, thereby leaving a remainder, said remainder surrounding said fluid channel and being generally conical in shape, such that said fluid channel is generally disposed along a central axis of the conical shape.

11. The method of Claim 10, wherein the step of removing a substantial portion of said substrate comprises the step of beveling a tip of said conical shape.

12. The method of Claim 10, wherein the step of providing a substrate comprises the step of providing a substrate comprising one of silicon and polysilicon.

13. The method of Claim 12, wherein the step of forming a fluid channel comprises the steps of:

- (a) forming a first mask;
- (b) etching the substrate through an orifice formed in the first mask to form said fluid channel; and
- (c) removing said first mask.

14. The method of Claim 12, wherein the step of removing a substantial portion of said substrate comprises the steps of:

- (a) forming a second mask;
- (b) depositing a nitride layer;
- (c) removing said second mask; and
- (d) etching said substrate to remove a substantial portion of said substrate.

15. The method of Claim 14, wherein the step of etching said substrate comprises the step of performing an anisotropic etch.

16. The method of Claim 14, wherein the step of etching said substrate comprises the steps of removing said nitride layer and performing an isotropic etch of the substrate.

17. The method of Claim 14, wherein the step of etching said substrate comprises the steps of:

- (a) performing an anisotropic etch of the substrate;
- (b) removing said nitride layer; and
- (c) performing an isotropic etch of the substrate.

18. A method of manufacturing an array of hollow microneedles, comprising the steps of:

- (a) providing a silicon substrate;
- (b) preparing a dotted mask on an upper surface of said silicon substrate, such that openings in said dotted mask correspond to desired locations for said hollow microneedles in the array;
- (c) etching said silicon substrate so as to form a plurality of fluid channels that extend substantially through said silicon substrate;
- (d) forming a nitride mask such that said nitride mask covers areas in which no nitride layer is desired;
- (e) forming a nitride layer, such that said nitride layer is deposited on the substrate in the areas not covered by the nitride mask;
- (f) removing said nitride mask;
- (g) performing a bevel etch upon said substrate, thereby forming an array of blunt, angular microneedles;
- (h) removing said nitride layer; and
- (i) performing a rounding etch to round and sharpen said blunt angular microneedles, thereby completing said array of hollow microneedles.

19. The method of Claim 18, wherein the silicon substrate has a thickness that is substantially equal to a desired height of the hollow microneedles comprising said array.

20. The method of Claim 11, wherein the step of providing a silicon substrate comprises the step of providing a silicon substrate having a thickness within a range from about 50 μm to about 100 μm .

21. The method of Claim 11, wherein in the array of blunt, angular microneedles, each microneedle has a base and a height, and wherein a width of said base is at least about equal to said height.

22. A minimally invasive diagnostic system for sampling and analyzing a biological fluid from a patient, comprising:

(a) a handheld diagnostic unit comprising a housing, a processor, a display electrically coupled to said processor, a keypad electrically coupled to said processor, and a memory electrically coupled to said processor;

(b) a disposable cartridge for obtaining a sample of said biological fluid from a patient, said disposable cartridge comprising a housing and an array of microneedles; and

(c) a sensor that when in contact with the sample of the biological fluid, produces a signal indicative of a characteristic of said biological fluid, said sensor being adapted to electrically couple with said processor to provide the signal to the processor for diagnostic processing.

23. The minimally invasive diagnostic system of Claim 22, wherein each microneedle of said array comprises:

(a) a generally conical-shaped body having a beveled, non-coring tip, said tip being sharp and able to pierce tissue;

(b) said conical body further having a broad base formed of a substrate at an opposite end from the tip; and

(c) a fluid channel extending through the conical-shaped body, providing fluid communication between said broad base and said tip.

24. The minimally invasive diagnostic system of Claim 23, wherein a height of the microneedle, which is defined as a distance from said broad base to said tip, is within a range from about 50 μm to about 100 μm .

25. The minimally invasive diagnostic system of Claim 23, wherein a height of each microneedle, which is defined as a distance from said broad base to said tip, is substantially less than a width of said broad base.

26. The minimally invasive diagnostic system of Claim 23, wherein said array of microneedles comprises silicon.

27. The minimally invasive diagnostic system of Claim 22, wherein said memory stores machine instructions that cause the processor to perform a diagnostic procedure using the signal, and indicate a result of the diagnostic procedure on the display.

28. The minimally invasive diagnostic system of Claim 27, wherein said diagnostic procedure determines a level of glucose in said biological fluid.

29. The minimally invasive diagnostic system of Claim 22, wherein said housing comprises a receptacle having a size and shape adapted to receive said disposable cartridge, and when said cartridge is inserted into said receptacle, said sensor is electrically coupled to said processor.

30. The minimally invasive diagnostic system of Claim 22, wherein said sensor is disposed in said disposable cartridge.

31. The minimally invasive diagnostic system of Claim 30 wherein said array of microneedles comprises a silicon substrate having a first surface on which said array of microneedles is formed, and a second surface on which said sensor is formed.

32. The minimally invasive diagnostic system of Claim 22, wherein said sensor is disposed in said housing.

33. A minimally invasive drug delivery system for transdermally delivering a medicinal fluid into a patient, comprising:

(a) a handheld control unit comprising a housing, a processor, a display electrically coupled to said processor, a keypad electrically coupled to said processor, a memory electrically coupled to said processor; a medicinal fluid reservoir, a medicinal fluid outlet in fluid communication with said medicinal fluid reservoir, and an actuator that develops pressure to force the medicinal fluid from the medicinal fluid reservoir and through the medicinal fluid outlet for infusion into the patient, said actuator being electrically coupled to and controlled by the processor;

(b) a disposable cartridge, said disposable cartridge comprising a housing, and an array of microneedles through which the medicinal fluid is infused into the patient; and

(c) a fluid line having a distal end and a proximal end, said proximal end being connected to said medicinal fluid outlet, and said distal end being coupled with said disposable cartridge to provide fluid communication between the medicinal fluid outlet and the disposable cartridge.

34. The minimally invasive drug delivery system of Claim 33, wherein each individual microneedle of said array comprises:

- (a) a generally conical-shaped body having a beveled, non-coring tip, said tip being sharp and able to pierce tissue;
- (b) said conical body further having a broad base formed of a substrate at an opposite end from the tip; and
- (c) a fluid channel extending through the conical-shaped body, providing fluid communication between said broad base and said tip.

35. The minimally invasive drug delivery system of Claim 34, wherein a height of the microneedle, which is defined as a distance from said broad base to said tip, is within a range from about 50 μm to about 100 μm .

36. The minimally invasive drug delivery system of Claim 34, wherein a height of each microneedle, which is defined as a distance from said broad base to said tip, is substantially less than a width of said broad base.

37. The minimally invasive drug delivery system of Claim 34, wherein a ratio of a height of each microneedle, which is defined as a distance from said broad base to said tip, to a width of said broad base ranges between about 1:1 to about 1:2.

38. The minimally invasive drug delivery system of Claim 33,

- (a) further comprising a data cable, said data cable having a proximal end and a distal end, said proximal end of the data cable being connected to said handheld control unit, such that said data cable is electrically coupled to said processor, said distal end of the data cable being electrically coupled to said disposable cartridge; and

- (b) said disposable cartridge further including an ultrasonic transducer array that produces an ultrasonic signal directed into target region within a body of a patient and receives a reflected ultrasonic signal from within the body of the patient, producing an output signal indicative of a condition of the target region, said ultrasonic transducer array being electrically coupled to said data cable through which the output signal is conveyed, said processor responding to the output signal and indicating to a user on the display that said disposable cartridge is disposed adjacent to a desired region within the body of the patient.

39. The minimally invasive drug delivery system of Claim 33, wherein said disposable cartridge further comprises at least one spring element that applies a biasing force to said array of microneedles, causing the microneedles to penetrate a dermal layer of a patient.

40. The minimally invasive drug delivery system of Claim 38, wherein said disposable cartridge further comprises a flow sensor for monitoring a flow rate of said medicinal fluid and producing a flow signal indicative thereof, said flow sensor providing the flow signal to the processor through the data cable.

41. The minimally invasive diagnostic system of Claim 40, wherein said array of microneedles comprises a silicon substrate having a first surface on which said array of microneedles is formed, and a second surface on which said flow sensor is formed.

42. The minimally invasive drug delivery system of Claim 33, wherein said disposable cartridge further comprises a valve for controlling a flow of said medicinal fluid into a patient.

43. The minimally invasive drug delivery system of Claim 33, wherein said medicinal fluid reservoir comprises a housing, a self sealing elastomeric membrane defining one portion of said medicinal fluid reservoir, and a sub-micron filter that prevents said medicinal fluid from exiting said medicinal fluid reservoir until said actuator develops a pressure that acts on said medicinal fluid.

44. The minimally invasive drug delivery system of Claim 33, wherein the medicinal fluid reservoir is removable from the handheld control unit and replaceable with a disposable diagnostic cartridge for use in obtaining a sample of a biological fluid from a patient, said disposable cartridge comprising a housing and an array of microneedles, a sensor being provided that when in contact with the sample of the biological fluid, produces a signal indicative of a characteristic of said biological fluid, said sensor being adapted to electrically couple with said processor to provide the signal to the processor for diagnostic processing.